



**Bio-Rad  
Laboratories**

*Diagnostics Group  
9500 Jeronimo Road  
Irvine, California 92618-2017  
Telephone: (714) 598-1200*

K980871

## 510(k) Summary

APR - 6 1998

Submitter

Bio-Rad Laboratories  
9500 Jeronimo Road  
Irvine, CA  
(714)598-1285  
Fax (714)598-1555

Contact Person

Elizabeth Platt

Date of Summary Preparation

March 24, 1998

Device (Trade & Common Name)

Lyphochek Whole Blood Control

Classification Name

CFR 862.1660: Quality Control Material  
(Assayed and Unassayed)

Devices to Which Substantial Equivalence is Claimed

Lyphochek Whole Blood Control  
Bio-Rad Laboratories, Irvine, CA  
K895905

Statement of Intended Use

Lyphochek Whole Blood Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

Description of the Device

Lyphochek Whole Blood Control is prepared from human whole blood with added pure chemicals. The control is provided in lyophilized form for increased stability.

Statement of How Technological Characteristics Compare to Substantial Equivalence Device



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A table is provided below comparing the similarities between the Bio-Rad Lyphocheck Whole Blood Control and the device to which substantial equivalence is claimed.

	Lyphocheck Whole Blood Control	Lyphocheck Whole Blood Control (new submission)
Intended Use	An assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	An assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Form	Lyophilized	Lyophilized
Matrix	Whole Blood	Whole Blood
Storage	2-8°C	2-8°C
Analytes	Cyclosporine, Lead, Red Cell Folate	Cyclosporine, FK-506, Lead, Red Cell Folate
Open Vial Claim	14 days when stored tightly capped at 2-8°C with the following exception: (1) red cell folate will be stable for 3 days.	14 days when stored tightly capped at 2-8°C with the following exception: (1) red cell folate will be stable for 3 days.
Differences	Previous product did not contain FK-506	Contains FK-506



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR - 6 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Elizabeth Platt  
Acting Regulatory Affairs/Quality Assurance Manager  
Bio Rad Laboratories  
9500 Jeronimo Road  
Irvine, California 92618-2017

Re: K980871  
Lyphochek Whole Blood Control  
Regulatory Class: I & III  
Product Code: DIF  
Dated: March 24, 1998  
Received: March 27, 1998

Dear Ms. Platt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

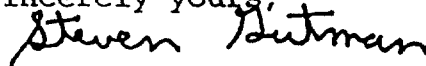
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical  
Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number: \_\_\_\_\_

Device Name: **Lyphochek Whole Blood Control**

**Indications for Use:**

Lyphochek Whole Blood Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

(PLEASE DO NOT WRITE BELOW THE LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
(Concurrence of CDRH, Office of Device Evaluation)

Prescription Use ✓

OR Over-The Counter Use \_\_\_\_\_

\_\_\_\_\_  
(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number

K980871